



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

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Appl. No. 08/942,369

Filed: October 2, 1997

For: **METHODS AND APPARATUS
FOR CONCURRENTLY
DETECTING PATHOGENIC
ORGANISMS AND
ANTIMICROBIAL
SUSCEPTIBILITY**

Art Unit: 1623

Examiner: M. Moran

Atty. Docket: 03604-0010-00US00

#32/D
Plunkett
4/7/01

Reply and Amendment Under 37 C.F.R. § 1.111

Commissioner for Patents
Washington, D.C. 20231

Sir:

In response to the Office Action dated September 26, 2000, (PTO Prosecution

File Wrapper Paper No. 29), Applicants submit the following Amendment and Remarks.

Applicants believe this Amendment and Response is accompanied by the appropriate petitions and fees. If extensions of time or fees for net addition of claims are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned for under 37 C.F.R. § 1.136(a), and any fees required therefor (including fees for net addition of claims) are hereby authorized to be charged to our Deposit Account No. 08-3038 referencing docket number 03604-0010-US00.

Amendments

Please amend the claims as indicated below. Support for this amendment is found at page 13, lines 9-12 and page 15, lines 4-18.

20. (Amended) A method of detecting the presence or urinary pathogens in a biological sample and of simultaneously determining the susceptibility of the urinary pathogens to antimicrobial agents, said method comprising:

providing a multicompartment assay device comprising: at least one compartment comprising a medium capable of sustaining growth of total microbial organisms; at least one compartment comprising a uropathogenic specific medium; and, at least one compartment comprising an antimicrobial susceptibility interpretation medium;

placing a portion of the biological sample respectively in said at least one compartment comprising a medium capable of sustaining growth of total microbial organisms; said at least one compartment comprising a uropathogenic specific medium; and, said at least one compartment comprising an antimicrobial susceptibility interpretation medium comprising an antimicrobial agent;

whereby metabolism of a signal generating substrate and production of a detectable signal in said at least one compartment comprising a medium capable of sustaining growth of total microbial organisms indicates the presence of microbial organisms in the sample; metabolism of a signal generating substrate and production of a detectable signal in said at least one compartment comprising a uropathogenic specific medium indicates the presence of urinary pathogens in the sample; and metabolism of a signal generating substrate and production of a detectable signal in said at least one compartment comprising an antimicrobial susceptibility interpretation medium indicates

that the organisms lack susceptibility to the antimicrobial agent comprised in said antimicrobial susceptibility interpretation medium; and

examining the compartments to determine the presence of urinary pathogens in said biological sample and the susceptibility of said urinary pathogens to said antimicrobial agents.

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Please add claim 31 as indicated. Support for this claim is found at p. 13, lines 22-27.

31. (New) The method of claim 20 wherein the signal generating substrate is fluorogenic or chromogenic.

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Remarks

Reconsideration of this Application is respectfully requested.

Claims 20-24 and 26 are pending in the application, with 20 being the independent claim.

Based on the amendment and following Remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and they be withdrawn.

Rejections Under 35 U.S.C. § 103

1. **Claims 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson in view of Libman and the Manual of Clinical Microbiology.**

This rejection is respectfully traversed. The present invention provides media and methods for the detection of the presence of urinary pathogens in a biological sample and the simultaneous determination of the susceptibility of those pathogens to microbial agents. The prior art deals with this problem by performing the four analytical steps